CDDF
Cancer Drug Development Forum

CDDF MULTI - STAKEHOLDER WORKSHOP

The Use of Real-World Data to Optimise Oncology Drug Development and Access

Amsterdam, Netherlands
21 - 22 November 2019

PROGRAMME

EVENT OUTLINE

Due to the current interest in Real World Data both from Industry but especially the EMA and FDA, the Cancer Drug Development Forum organizes a multi-stakeholder workshop on the Use of Real-World Data to Optimise Oncology Drug Development and Access on 21-22 November, 2019 in Amsterdam, NL.

The aim of the workshop is to have a multi-stakeholder discussion representing regulators, clinicians, HTA / payers, and policy makers on the challenges of developing RWD proposals in oncology and share current experience on the best sources of RWD of high quality in oncology drug development.

The discussion will focus particularly on issues concerning methodology of collecting good quality and relevant information, and the specific requirement of regulators to maximise the use of RWD in licensing decisions. We will also explore possible solutions to the current challenges and collaboratively search for agreements.

PROGRAMME COMMITTEE

- John Smyth (University of Edinburgh - CDDF Board, UK) - Programme Chair
- Nafsika Kronidou Horst (Roche, CH)
- Stefan Schwoch (Lilly, UK)
- Eva Skovlund (Norwegian University of Science and Technology, NO)

TARGET AUDIENCE

The target is a multidisciplinary audience of patient associations, academia representatives, EU and US regulatory bodies (EMA, FDA & national agencies), pharmaceutical industry, and HTAs.

WORKSHOP VENUE & HQ HOTEL

Room Mate Aitana Hotel
www. room-matehotels.com/en/aitana/
Address: IJDok 6 1013 MM - Amsterdam, Netherlands.
Phone: (+31) (0) 20 89 14 800

MEETING SECRETARIAT

Cancer Drug Development Forum (CDDF)
c/o BLSI
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PROGRAMME

Day 1 Thursday 21 November 2019

MEETING ROOM: OSCAR

13:00 **Welcome Note**
John Smyth (CDDF Board, UK)

13:15 **Overview of the Current RWD Landscape**
Nafsika Kronidou Horst (Roche, CH)

SESSION 1: THE CURRENT POSITION AND KEY CHALLENGES

Session-chairs : John Smyth (CDDF, UK) & Nafsika Kronidou Horst (Roche, CH)

Current Attitudes and Key Challenges : Regulators & Payers Perspective

13:30 **European Medicines Agency**
Ralf Herold (EMA, NL)

13:50 **Health Technology Assessment**
Carin Uyl-de Groot (Erasmus Universiteit Rotterdam, NL)

14:10 Q&A Session / Discussion (10')

Current Attitudes and Key Challenges : Clinician's Perspective & Industry Case Studies

14:20 **Clinician's Perspective on RWD Repositories**
Jaap Verweij (Erasmus Universiteit Rotterdam/CDDF, NL)

14:40 **Industry Case Study 1: Real-World Comparator in a Single-Arm Study**
Valérie André (Lilly, FR)

14:50 **Industry Case Study 2: A Pan-Cancer Registry Proposal**
Marlene Thomas (Roche, CH)

Current Attitudes and Key Challenges : Patient Perspective

15:00 **Patient Perspective**
Roger Wilson (UK)

15:10 Coffee Break (20')

SESSION 2: METHODOLOGICAL ISSUES

Session-chairs : Eva Skovlund (Norwegian University of Science and Technology, NO)
& Ralf Herold (European Medicines Agency, NL)

15:30 **Introduction to Methodological Challenges**
Eva Skovlund (NTNU, NO)

DATA COLLECTION

15:35 **Disease-Based Registries**
Espen Enerly (Norwegian Cancer Registry, NO)

16:05 **Product-Based Registries**
Elmar Schmitt (Merck Healthcare KGaA, DE)

16:30 **Wearables and Patient Reported Outcomes: New Wins?**
Cécile Ollivier (Aparito, NL)

16:55 Q&A Session / Discussion (15')

DATA ANALYSIS

17:10 **Statistical Considerations in Building External Control**
Chris Harbron (Roche, UK)

17:35 **Electronic Healthcare Records**
Meghna Samant (Flatiron Health, US)

18:00 **Introduction of Breakout Sessions (30')**

19:00 Welcome Drinks (private dining room at I-Dock restaurant, Room Mate)

19:30 Networking Dinner (private dining room at I-Dock restaurant, Room Mate)

Day 2 Friday 22 November 2019

SESSION 3: IDENTIFYING SOLUTIONS - BREAKOUT SESSIONS

09:00 **Identifying Solutions - 4 Breakout Sessions**
Moderator: Gracy Crane (Roche, UK)

See the detailed information regarding the breakout sessions on the next page.

11:00 **Coffee Break**

11:30 **Consolidating Outcomes from Breakout Sessions**

12:30 **Wrap-up and Next Steps**
John Smyth (CDDF, UK)

13:00 Lunch (I-Dock restaurant, Room Mate)

BREAKOUT SESSIONS

SESSION 1 : REGULATORY AND HTA ENVIRONMENT FOR THE USE OF RWE

Meeting room: Oscar (ground floor)

Chairs: Stefan Schwoch (Lilly, UK) & Larissa Higgins (Health Products Regulatory Authority, IL)

This breakout session will explore what the current environment is, look at enablers/ opportunities, barriers/uncertainties, examples/ case studies and possible solutions/ recommendations. We will discuss pre- and post-marketing and cover similarities and differences for the areas of regulatory review and HTA.

SESSION 2 : PATIENT VOICE

Meeting room: Valeria (ground floor)

Chairs: Roger Wilson (UK) & Irmela Radtke (Roche, CH)

With the aim of achieving better treatments, better information to support patients, and more meaningful outcomes, this session will explore and analyze possible solutions in the context of patient-centred research, pathway approach, funding and new challenges to be addressed.

SESSION 3 : ENSURING ROBUST DECISION MAKING FROM THE ANALYSIS OF RWD

Meeting room: Emma (1st floor)

Chairs: Chris Harbron (Roche, UK) & Eva Skovlund (NTNU, NO)

In this session, participants will discuss some of the key criteria that need to be in place in order to make robust decisions from RWD:

- In which settings could using RWD be most valuable?
- How can we avoid biases?
- When biases are unavoidable?
- How do obtain a realistic estimate of the uncertainty of any conclusions?
- How do we communicate our levels of confidence to internal and external stakeholders

SESSION 4 : DATA COLLECTIONS SYSTEMS

Meeting room: Isabella (1st floor)

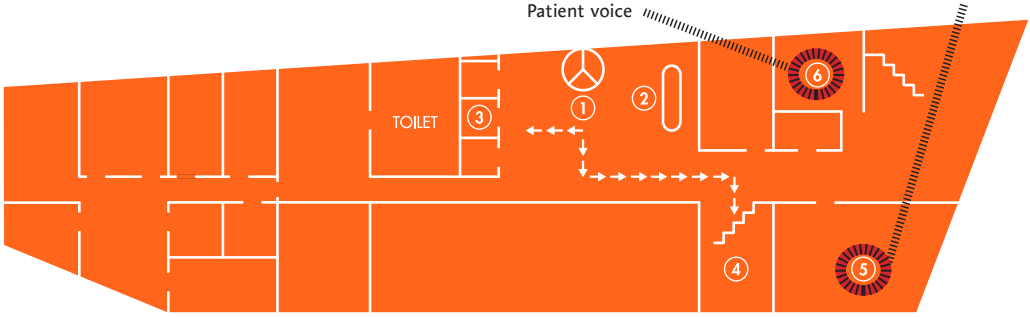
Chairs: Meghna Samant (Flatiron, US) & Bjørg Bolstad (Norwegian Medicines Agency, NO)

This session will focus on real world data collection systems that exist today in Europe and US along with current and future uses of these data to facilitate regulatory and reimbursement decision making. Most importantly, the session will build upon key challenges identified and will propose solutions for the wider adoption of these data to accelerate drug development and patient access.

MEETING ROOMS GROUND FLOOR MAP

BREAKOUT SESSION 1
OSCAR
Regulatory and HTA environment for use of RWE

BREAKOUT SESSION 2
VALERIA
Patient voice

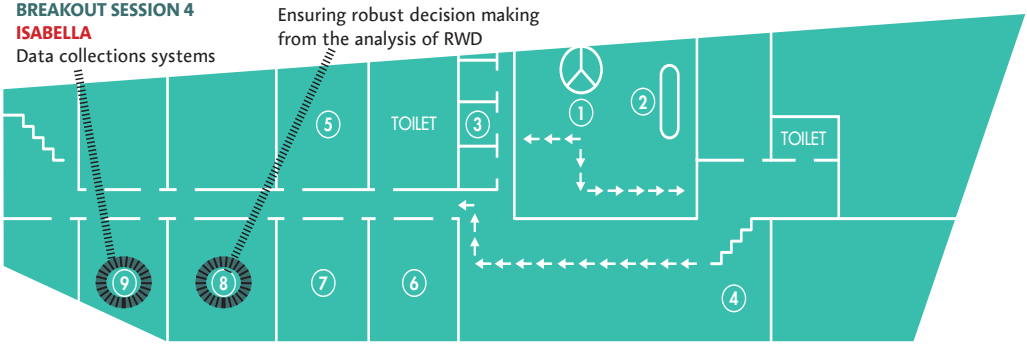


1. ENTRANCE
2. FRONT DESK
3. ELEVATORS
4. STAIRS
5. OSCAR MEETING ROOM — BREAKOUT SESSION 1
6. VALERIA MEETING ROOM — BREAKOUT SESSION 2

MEETING ROOMS FIRST FLOOR MAP

BREAKOUT SESSION 3
EMMA
Ensuring robust decision making from the analysis of RWD

BREAKOUT SESSION 4
ISABELLA
Data collections systems



1. ENTRANCE
2. FRONT DESK
3. ELEVATORS
4. STAIRS
5. GRACE MEETING ROOM
6. ALICIA MEETING ROOM
7. CARLA MEETING ROOM
8. EMMA MEETING ROOM — BREAKOUT SESSION 3
9. ISABELLA MEETING ROOM — BREAKOUT SESSION 4

NOTES

JOIN OUR MULTI-STAKEHOLDER DISCUSSIONS TO ACCELERATE THE DELIVERY OF EFFECTIVE AGENTS TO PATIENTS!

10-12 FEBRUARY 2020
NOORDWIJK AAN ZEE

CDDF 11TH SPRING CONFERENCE 2020

CDDF Spring Conference 2020 is a unique forum that convenes every 18 months and gathers the leaders in the world of innovative cancer therapy development, including medical researchers, pharmaceutical industry representatives, regulatory authority representatives as well as patient advocacy groups. It is the successor of the former CDDF Alpine Conference and the 11th edition takes place from 10 to 12 February 2020 in Noordwijk aan Zee, the Netherlands.

This multi-stakeholder, interactive meeting offers plenary lectures with moderated discussions and case studies along with networking opportunities.

Discussion Topics:

- Combination Therapies
- Tumor Agnostic Drug Development
- Cell Therapies
- Revision of Anticancer Guidelines

Key Information:

- Date: 10-12 February 2020
- Location: Noordwijk aan Zee, NL
- Venue: Radisson Blu Palace Hotel
- Registration: until January 27, 2020

Stay Informed about the CDDF 11TH Spring Conference 2020!

→ WWW.CDDF.ORG